



Application No.: 08/851628

Atty Docket No. III-P01-515

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the claims:

MAY 15 2003

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Please amend the claims as follows in accordance with 37 CFR §1.121.

1. (Currently amended) A method of improving renal function in a mammal in, or at risk of, chronic renal failure comprising administering to said mammal a therapeutically effective amount of a morphogen, said morphogen comprising an amino acid sequence having at least 70% amino acid sequence homology with the C-terminal seven-cysteine skeleton of human OP-1, the sequence of the C-terminal seven-cysteine skeleton of human OP-1 being set forth at amino acids 330-431 of SEQ ID NO:1; wherein said mammal [is not a kidney transplant recipient, and] is afflicted with a chronic renal condition characterized by the progressive loss of renal function associated with the progressive loss of functioning nephron units, [;] wherein said morphogen induces chondrogenesis in an *in vivo* ectopic bone assay, [;] and wherein said therapeutically effective amount causes a clinically significant improvement in a standard marker of renal function in said mammal, so as to thereby improve renal function in the mammal.

2. (Currently amended) A method of [treatment to] delaying the need for, or reducing[e] the frequency of, chronic dialysis treatments in a mammal in, or at risk of, chronic renal failure comprising administering to said mammal a therapeutically effective amount of a morphogen, said morphogen comprising an amino acid sequence having at least 70% amino acid sequence homology with the C-terminal seven-cysteine skeleton of human OP-1, the sequence of the C-terminal seven-cysteine skeleton of human OP-1 being set forth at amino acids 330-431 of SEQ ID NO:1, [;] wherein said mammal is [not a kidney transplant recipient, and is] afflicted with a chronic renal condition characterized by the progressive loss of renal function associated with the progressive loss of functioning nephron units, [;] wherein said morphogen induces chondrogenesis in an *in vivo* ectopic bone assay; and wherein said therapeutically effective amount causes a clinically significant improvement in a standard marker of renal function in said mammal such that said mammal's need for chronic dialysis is delayed or reduced, so as to thereby delay the need for, or reduce the frequency of, chronic dialysis treatments in the mammal.

3. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen comprises a polypeptide comprising at least a C-terminal seven-cysteine domain of a protein selected from the group consisting of OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP8, BMP9, GDF-5, GDF-6, GDF-7, DPP, Vg1, Vgr-1, 60A, GDF-1, GDF-3, GDF-5, GDF-6, GDF-7, BMP-10, [BMP11,] BMP13, BMP15, UNIVIN, NODAL, SCREW, ADMP, and NEURAL.

4. (Currently amended) [A] The method [as in] of claim 3, wherein said morphogen comprises a polypeptide consisting of at least a C-terminal seven cysteine domain of a protein selected from a group consisting of a pro form, a mature form, and a soluble form of human OP-1.

5. (Canceled)

6. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen has at least 75% homology with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1.

7. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen has at least 80% homology with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1 .

8. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen has at least 60% identity with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1 .

9. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen has at least 65% identity with an amino acid sequence of a C-terminal seven-cysteine domain of human OP-1 .

10. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen has at least 70% identity with an amino acid sequence of a C-terminal seven-cysteine-domain of human OP-1.

11. (Canceled)

12. (Currently amended) [A] The method [as in] of claim 1, wherein said morphogen is selected from the group consisting of OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMP5, BMP6, BMP8, BMP9, GDF-5, GDF-6, GDF-7, DPP, Vgl, Vgr-1, 60A, GDF-1, GDF-3, GDF-5, GDF-6, GDF-7, BMP10, [BMP11,] BMP13, BMP15, UNIVIN, NODAL, SCREW, ADMP, and NEURAL.

13-14. (Canceled)

15. (Currently amended) [A] The method [as in] of claim 1, wherein examination of said mammal indicates renal fibrosis.

16. (Currently amended) [A] The method [as in] of claim 15, wherein said examination is an ultrasound, MRI or CAT scan of said mammal.

17. (Currently amended) [A] The method [as in] of claim 1, wherein said mammal has less than about 50% possesses a number] of the functional nephron units [which is less than about 50% of a number of functional nephron units present in] of a mammal having intact healthy kidneys.

18-23. (Canceled)

24. (Currently amended) [A] The method [as in] of claim 1, wherein said mammal has a GFR which is chronically less than about 50% of a GFR_{exp} for said mammal.

25-27. (Canceled)

28. (Currently amended) [A] The method [as in] of claim 1, wherein said mammal is a human male weighing at least about 50 kg and has a GFR which is chronically less than about 50 ml/min.

29-31. (Canceled)

32. (Currently amended) [A] The method [as in] of claim 1, wherein said mammal is a human female weighing at least about 40 kg and has a GFR which is chronically less than about 40 ml/min.

33-51. (Canceled)

52. (Currently amended) [A] The method [as in] of claim 1, wherein said renal therapeutic agent is OP-1.

53. (Currently amended) [A] The method [as in] of claim 2, wherein said renal therapeutic agent is OP-1.

54. (Currently amended) [A] The method [as in] of claim 1, wherein said chronic renal condition is selected from the group consisting of: chronic diabetic nephropathy, diabetic glomerulopathy, diabetic renal hypertrophy, hypertensive nephrosclerosis, hypertensive glomerulosclerosis, renal dysplasia, glomerular hypertrophy, tubular hypertrophy, glomerulosclerosis and tubulointerstitial sclerosis.

55. (Currently amended) [A] The method [as in] of claim 2, wherein said chronic renal condition is selected from the group consisting of: chronic diabetic nephropathy, diabetic glomerulopathy, diabetic renal hypertrophy, hypertensive nephrosclerosis, hypertensive glomerulosclerosis, renal dysplasia, glomerular hypertrophy, tubular hypertrophy, glomerulosclerosis and tubulointerstitial sclerosis.